REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated February 26, 2007, is respectfully requested in view of this amendment. By this amendment, claims 1, 7 and 13-15 have been amended, and new claims 16-18 have been inserted. Claims 1-18 are pending in this application.

The amendment to claim 1 sets forth the feature of administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Support is found in the specification, *inter alia* at Standard Paragraph [0044]. Claim 7 is now set forth as a method for administering a treatment to a patient including administration of a neurotoxin including the Botulinum toxin intramuscularly, intravenously, or subcutaneously, and simultaneously and in combination with said administering the Botulinum toxin, exposing the patient to electromagnetic signals. Dependent claims 13-15 also describe the Botulinum toxin as applied as a neurotoxin adjuvant to said exposing the patient to electromagnetic signals. Support is found in the specification, *inter alia* at Standard Paragraphs [0044] and [0056]. New dependent claims 16-18 reflect features found in claims 13-15, and depend from claim 1. It is respectfully submitted that the above amendments introduce no new matter within the meaning of 35 U.S.C. §132. This Supplemental Response also corrects a formal error in the preamble of Claim 1.

In the outstanding Office Action, claims 7-15 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 7-15 were rejected under 35 U.S.C. §101 because the claimed recitation was of a use, without setting forth any steps involved in the process. Claims 1, 2, and 6 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,443,883 (Ostrow et al., hereinafter *Ostrow*) and claims 1, 3, and 6 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2004/0077921 (Becker et al., hereinafter *Becker*). Claims 7, 8, and 12 – 15 were rejected under 35 U.S.C. §103(a) as obvious over *Ostrow* in view of U.S. Patent No. 6,464,986 (Aoki et al., hereinafter *Aoki*). Claims 7, 9, and 12–15 were

rejected under 35 U.S.C. §103(a) as obvious over *Becker* in view of *Aoki*. Claims 1–5 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,674,482 (Waltonen et al., hereinafter *Waltonen*). Claims 7–11 and 13–15 were rejected under 35 U.S.C. §103(a) as obvious over *Waltonen* in view of *Aoki*.

Rejections Under 35 U.S.C. §101 and 112

The Examiner rejected claims 7-15 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claims 7-15 were rejected under 35 U.S.C. §101 because the claimed recitation was of a use, without setting forth any steps involved in the process. Specifically, the reference to provision of a pharmaceutical composition without setting forth steps involved in the method or process was deemed unclear.

Response

Reconsideration and withdrawal of the rejection are respectfully requested.

35 U.S.C. §101 states, "... any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ... .". 35 U.S.C. §112, second paragraph, states that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claim 7, as amended, now set forth active, positive steps delimiting how the subject matter is practiced. It is submitted that amended claim 7 now particularly points out and distinctly claims the subject matter. Claims 8-15 depend from claim 7 and the §§101 and 112 issues for these claims are believed resolved by the amendments to claim 7.

Rejections under 35 USC §102

Claims 1, 2, and 6 were rejected under 35 U.S.C. §102(e) as being anticipated by *Ostrow*. *Ostrow* is cited as disclosing treatment for osteoporosis comprising the use of electromagnetic signals at a frequency of 1-30 Hz and at a field strength of 1-20 G. *Ostrow* is also cited as showing a quasi-rectangular modulation form and modulated pulses.

Claims 1, 3, and 6 were rejected under 35 U.S.C. §102(e) as being anticipated by *Becker*. *Becker* is cited as disclosing the use of electromagnetic signals by pulsating impulse modulated direct current at 1-30 Hz and 1-20 G.

Response

This rejection is traversed as follows. For a reference to anticipate an invention, all of the elements of that invention must be present in the reference. The test for anticipation under section 102 is whether each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131.

Claim 1, as amended recites:

> "... exposing a patient to electromagnetic signals ... and administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals."

The cited references to *Ostrow* and *Becker* fail to show or suggest the use of Botulinum as an adjuvant to the application of the electromagnetic signals. Accordingly, the *Ostrow* and *Becker* references do not teach or suggest all the features as recited in claims 1, 2 and 6 of the present claims. It is therefore respectively submitted that the rejection under 35 U.S.C. §102 should be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 7, 8, and 12 – 15 were rejected under 35 U.S.C. §103(a) as obvious over *Ostrow* in view of *Aoki*. Claims 7, 9, and 12–15 were rejected under 35 U.S.C. §103(a) as obvious over *Becker* in view of *Aoki*. Claims 1–5 were rejected under 35 U.S.C. §103(a) as obvious over *Waltonen*. Claims 7–11 and 13–15 were rejected under 35 U.S.C. §103(a) as obvious over *Waltonen* in view of *Aoki*. These rejections, as applied to the amended claims, are respectfully traversed.

Response

This rejection is traversed as follows. To establish a *prima facie* case of obviousness, the Examiner must establish: (1) some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) the prior art references teach or suggest all of the claim limitations. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine,* 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. *See Dystar Textilfarben GMBH v, C. H. Patrick*, 464 F.3d 1356 (Fed. Cir. 2006). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. *Id.* at 1366.

As described above, both *Ostrow* and *Becker* describe electromagnetic pulses, but fail to show or suggest the use of a neurotoxin adjuvant (claims 13-18), or the use of the pulses in combination with administration of a neurotoxin.

Aoki is cited for the use of Botulinum for treatment of pain associated with osteoporosis. This fails to suggest the claimed subject matter because there is no suggestion that administration of a neurotoxin be combined with the application of electromagnetic pulses, or the use of the neurotoxin as an adjuvant to electromagnetic therapy.

Further, the example cited (col. 24, ll 15-30) describes treatment of pain due to an arthritic condition. Osteoarthritis is described but there is no indication that the pain caused by the osteoarthritis is what is being treated. The general description is reduction of pain by reducing the nerve activity other than that caused by motor neurons, with suggestion of "an antinociceptive effect". (See col. 16, lines 19-28.) Regardless of the characterization of the pain, the treatment described in *Aoki* is of the non-spasm pain, and not of the osteoporosis.

Waltonen is cited as showing exposing a patient to electromagnetic signals, but not showing a particular range. It is respectfully submitted that *Waltonen* also fails to suggest the administration of a neurotoxin in combination with the application of the electromagnetic pulses, or the use of the neurotoxin as an adjuvant to electromagnetic therapy.

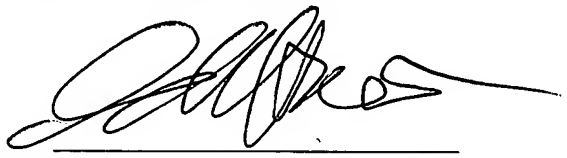
Aoki is cited for the use of Botulinum, but fails to suggest the combination of neurotoxin in combination with the application of the electromagnetic pulses, or the use of the neurotoxin as an adjuvant to electromagnetic therapy. Therefore, the combination fails to suggest the claimed invention because there is no suggestion that administration of a neurotoxin be combined with the application of electromagnetic pulses, or the use of the neurotoxin as an adjuvant to electromagnetic therapy.

Applicants therefore respectfully submit that the cited references do not teach or suggest all the features as recited in claims 1-18 of the present invention. It is therefore respectively submitted that the rejection under 35 U.S.C. 103(a) should be withdrawn.

CONCLUSION

In light of the foregoing, Applicants submit that the application is in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicants respectfully request that the Examiner call the undersigned.

Respectfully submitted,
THE NATH LAW GROUP



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